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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION N |
|-----------------|-------------|--------------------------|---------------------|----------------|
| 10/025,669 | 12/18/2001 | Kari Aarne Juhani Laakso | 25,416 | 6543 |

7590 10/04/2004

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| EXAMINER |
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HO, UYEN T

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,669

Applicant(s)

JUHANI LAAKSO ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose an apparatus for delivering a self-expanding stent having the inner tube that does not extend distally of the capturing element.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an apparatus for delivering a self-expanding stent including the distal tube extend distally of the capturing element, does not reasonably provide enablement for an apparatus for delivering a self-expanding stent including an inner tube that does not extending distally of the capturing element. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification does not disclose an apparatus for delivering a self-expanding stent having the inner tube that does not extend distally of the capturing element.

Claim Rejections - 35 USC § 103

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 7-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (5,683,451) in view of Fitz (6,306,163) further in view of Broome (6,391,050). Lenker et al. disclose an apparatus and method for delivering a self-expanding stent-graft, the apparatus including an outer tube, an inner tube, a capturing element and the runners/bent wires to assist delivering the stent-graft. Although, Lenker et al. does not disclose a foldable sleeve and a blocking element as claimed, Fitz disclose an apparatus for delivering a self-expanding stent including bent wires (42) and a foldable sleeve/restraining sheath disposed on the bent wires for delivering the stent as well as for capture the emboli; Broome discloses an apparatus for stent delivering including a bumpers for preventing movement of stent in a proximal direction when outer sheath is retracted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Lenker et al.'s apparatus by employ a foldable sleeve/restraining sheath as disclosed by Fitz in order to deploy a self expanding stent in a vessel while preventing embolic migration using the foldable sleeve/restraining sheath and it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a bumpers as disclosed by Broome into the apparatus for preventing movement of stent in a proximal direction when outer sheath is retracted.

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In regard to claim 14, it is well known in the art to have apertures on the filter membrane for capturing emboli in order to allow the fluid to pass through and the emboli to be captured. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ apertures on the foldable sleeve in order to capture emboli while allow the fluid to pass through

In regard to method claims, all the steps as claimed are inherently carried out when the apparatus of Lenker et al. in view of Fitz , further in view of Broome is used.

Allowable Subject Matter

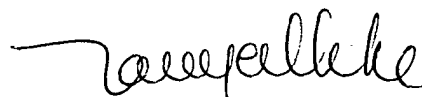
6. Claims 4-6 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior ad fails to disclose or suggest a carriage being adapted to engage an outer tube so as to resist distal movement of the capturing element relative to the outer tube.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

September 28, 2004